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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,736	08/17/2001	Weiping Shao	469290-76	3038

7590 06/30/2003
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6 Becker Farm Road
Roseland, NJ 07068

EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/30/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/931,736	SHAO, WEIPING	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) 19-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-18, in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 2-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claims 2-8 recite "an antibody" is indefinite because it is unclear if applicant is referring to the same antibody as in claim 1 or a different antibody. If this is the same antibody, said limitation should recite "said antibody" or "the antibody". Please correct.
6. Claims 14 and 16 recite "tether" in line 2 is indefinite because it is unclear as to what this term means. Further, this term is not defined in the specification in such a way that one skilled in the art would understand. Please clarify.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 8-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorval et al (USP#5,561,045).

Dorval et al teaches a blocked immunoglobulin that has an antibody portion and a Protein A portion, which are used to detect a plurality of analytes (col. 5, lines 47-50). Protein A is bound to the Fc region of an immunoglobulin of a class that specifically binds to a predetermined analyte (col. 4, lines 28-40). Protein A may be immobilized on a support to be used in a test assay to capture binding partners of either the immunoglobulin or Protein A (col. 9, lines 1-12). Both immunoglobulin and the protein will be bound to a support by hydrophobic coupling, but will be free of interaction between them, such as hydrophobic coupling. The antibody portion of the

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immunoglobulin has at least one antigenic reactive site because both immunoglobulin and the Protein A portion will be free to interact specifically with analytes in a sample (col. 5, lines 31-40). The preferred supports are plates, polymeric beads, porous membranes (col. 6, lines 35-47). The binding of antibodies to molecular species typically involve the highly specific interaction of the variable portion of the antibody wherein this interaction is responsible for specific recognition by antibodies of foreign substances (col. 5, lines 31-36).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 8-10 rejected under 35 U.S.C. 102(b) as being anticipated by Sano et al (USP#665,539).

Sano et al teaches a blocked immunoglobulin that wherein streptavidin-protein A binds to an antibody portion of its immunoglobulin G-binding domain (col. 1, lines 61-65). The antibody portion of the immunoglobulin contains an antigen-reactive fragment that is able to form an antigen-antibody complex that can comprise of DNA, RNA, fragment, analogue or a derivative (col. 3, lines 1-4). Streptavidin-Protein A comprises at least one protein A compound wherein it binds to biotin (col 4, lines 32-37). Streptavidin-Protein A can be a fragment because Sano et al discloses that any material

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which is able to specifically recognized or which possesses both antibody-binding domains and also the biotin-binding domains are suitable for use with this present invention (col. 4, lines 22-31).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sano et al and Dorval et al in view of Cabilly et al (USP#4,816,567).

The teachings of Dorval et al and Sano et al are set forth above, but are silent with respect to the number of light and heavy chain variable regions of the antibody.

However, Cabilly et al teaches altered and native immunoglobulins that include constant-variable regions that are immunologically capable of binding predetermined antigens (see summary). Cabilly et al teaches that one pair of heavy and light chain is homologous to antibodies raised against one antigen, while other pairs of heavy and light chain is homologous to those raised against another antigen. This results in the ability to bind two antigens simultaneously. The variable region has the advantage the ease of preparation and has good specificity (col. 6, lines 35-68) and their pairs of heavy and light chains can simultaneously react with more than one antigen (col. 15, lines 45-50).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Dorval et al and Sano et al to include altered immunoglobulin antibodies as taught by Cabilly et al that contain variable regions of heavy and light chains because they have high sensitivity and are capable of being reactive to more than one antigen simultaneously. Another advantage is that they are easy to prepare (col. 6, lines 65-66).

Conclusion

13. No claims are allowed.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. James S. Huston (USP#5,476,786) teaches a family of synthetic proteins having affinity for preselected antigens. These proteins comprise of amino acid sequences that have variable heavy and light chains.

B. Kenten et al (USP#6,087,476) teaches luminescent chimeric proteins which include light or heavy chain immunoglobulin with protein A.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

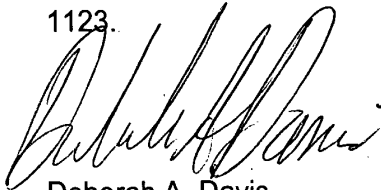
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for

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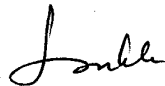
the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123.



Deborah A. Davis
CM1, 7D16
June 18, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
06/27/03